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AS

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/230,137 08/10/99 CUNNINGHAM

R 23861-001

EXAMINER

IM22/0522

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ART UNIT

PAPER NUMBER

1743

8

DATE MAILED:

05/22/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/230,137

Applicant(s)

Cunningham

Examiner

LaToya I. Cross

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 August 1999.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____.

DETAILED ACTION

Priority

- OK 1. Applicants' claim for foreign priority is acknowledged. A statement reading "This is a 371 of PCT/GB97/01939, filed July 16, 1997 and claiming priority to United Kingdom application 9614851.5 filed July 17, 1996." should be entered following the title of the invention or as the first sentence of the specification.

Specification

- OK 2. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 8 and 19-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- OK 5. Regarding claim 8, the phrase "or the like" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "or the like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

Claims 19-25 recite " a pouch that is of size and shape that corresponds to the

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size and shape of the test device according to claim 1". The claim is indefinite because the pouch is not defined structurally. Claim 1 recites "predetermined size and shape" which includes all sizes and shapes. Thus the pouch is not clearly defined.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 19-25 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,520,041 to Haswell.

Applicant's claimed invention is directed to a pouch of a predetermined size and shape.

Haswell '041 teaches a pouch for sample card having a predetermined size and shape. The pouch is equipped with a desiccant packet. The pouch is lined with a fluid impervious material. See col. 5, lines 9-20.

Therefore, for the reasons set forth above, Applicants' claimed invention is

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-18 and 26-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,460,057 to Ostrup in view of US Patent 5,334,502 to Sangha.

Applicant's claimed invention is directed to a test device comprising a substrate; an indentation/aperture in said substrate; supportive material mounted on said substrate; guide means; and sample indicating means.

Ostrup '057 discloses an apparatus for handling biological samples. The apparatus includes a sample collection unit/card (20) comprising a substrate (22) and several apertures (25). Absorbent filter paper (30) is disposed over each aperture. The card is provided with a mark (34) for providing the location of acceptable sample and an optimum point for punching (35). Marks (34, 35) are used by the camera to determine the ideal location for punching out the portion of the filter paper containing the sample. *assembly fig. 6 + package fig. 8*

Ostrup '058 does not teach a guide means having a sample deposition portion connected to a channel portion.

Sangha '502 teaches a device for collecting biological samples. The device of Sangha '502 comprises an absorbent layer (30) onto which sample is deposited. As the user deposits sample onto the center portion (32) of the absorbent layer, a one way

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barrier (38) leads the sample to the indicator (39) where a colored signal will denote the presence of a sufficient amount of sample.

It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to use such a guide means, as disclosed by Sangha '502, in the sample collection card of Ostrup '057 for the purpose of alerting the user of the presence of a sufficient amount of sample on the card. Such a modification would provide an easy manner for determining the amount of sample that has been collected.

Therefore, for the reasons set forth above, Applicant's claimed invention is deemed to be obvious, within the meaning of 35 USC 103, in view of the teachings of Ostrup '057 and Sangha '502.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 703-305-7360. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 703-308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-5408 for regular communications and 703-305-3599 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

LIC *SLC*
May 21, 2001

Jill Warden
Jill Warden
Supervisory Patent Examiner
Technology Center 1700